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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/718,803

11/22/2000

Paul O. Sheppard

A-935 US

2602

37500

7590

05/17/2006

AMGEN INC.
LAW DEPARTMENT
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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/718,803

Applicant(s)

SHEPPARD ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>5/11/06</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 03/03/06. Claims 1, 3-5, 7 and 9 have been amended. Claims 2, and 8 have been canceled. Claims 1, 3-7 and 9-10 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al. (WO 98/42840A1).

3. Claims 1, 3 and 6 are directed to a method of forming a peptide-receptor complex, wherein the method comprises contacting the peptide comprising the amino acid residues 24-37 of SEQ ID NO: 2 and GHS-R, wherein said receptor is expressed in many tissue including stomach and small intestine etc. and it is mobilized onto the cell membrane.

4. (WO 98/42840A1) teach a method comprises administering a peptide having the same amino acid residues 24-37 of SEQ ID NO: 2 to the stomachs of rats for testing the stomach contractions or administering said peptide to mice orally for determining the glucose challenge response (See (examples 4, 5, 7-8 on pages 45-46, pages 48-49 and claim 17), they found that the administered peptide induces the stomach contraction and increases the glucose adsorption in the tested animal models. Because the stomach tissue and GI tract inherently express the GHS-Rs on the cell membranes of the cells located along the stomach and GI tract, the claimed invention is inherently anticipated by the cited reference.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (WO 98/42840A1) in view of the disclosure by Arena et al. (WO 97/21730A10).

7. Claims 1, 3 and 6 are directed to a method for forming a peptide-receptor complex, wherein the peptide comprising contacting the peptide comprising the amino acid residues 24-37 of SEQ ID NO: 2 and the receptor is GHS-R having the amino acid sequence of SEQ ID NO: 5, which is expressed on the cell membrane.

8. (WO 98/42840A1) teach a method comprises administering a peptide having the same amino acid residues 24-37 of SEQ ID NO: 2 to the stomachs of rats for testing the stomach contractions or administering said peptide to mice orally for determining the glucose challenge response (See (examples 4, 5, 7-8 on pages 45-46, pages 48-49 and claim 17), they found that the administered peptide induces the stomach contraction and increases the glucose adsorption in the tested animal models. The stomach tissue and GI tract inherently express the GHS-Rs on the cell membranes of the cells located along the stomach and GI tract. Sheppard et al. do not teach the GHS-R has amino acid sequence of SEQ ID NO: 5.

9. Arena et al. disclosed variety of the GHS-Rs and their sequences, including the claimed human HGS-R of SEQ ID NO: 5.

10. Therefore, it would have been obvious for a person with ordinary skill in the art to use the human cell line that expresses a human GHS-R with amino acid sequence of SEQ ID NO: 5 onto a cell membrane for doing a peptide receptor binding assay with the peptide of SEQ ID NO: 2. Because the peptide of SEQ ID NO: 2 is isolated from the human cDNA library disclosed by Sheppard et al. and Sheppard et al, also teach that said peptide is able to work on the rat or mice GI tract, it would have also be obvious for a person with an ordinary skill in the t art to

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understand that said peptide would work on human by nature. Hence absence of the unexpected result to the contrary, the claimed invention as a whole is considered to be prima facie obvious absence unexpected results.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process of cell or peptide is separated from its binding partner.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. The claimed invention in claims 1 and 3-6 are directed to non-statutory subject matter. Because the process that lets a peptide and its receptor naturally binding each other could occur naturally inside any animal or human body. In the instant case, the peptide cited in claim 1 is not an isolated or synthetic one and claim 1 only cite to contact a peptide with a receptor, i.e. GHS-R expressed on the cell membrane. Because both the claimed peptide and receptor GHS-R are naturally present in an animal or human body and the process occurs naturally inside the body, the claimed invention is directed to a non-statutory subject matter.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**BAOQUN LI, MD
PATENT EXAMINER**

Bao Qun Li

5/12/2006

